REMARKS

Applicants request reconsideration and withdrawal of the rejection of claims 20-26 and 28-29 under 35 U.S.C. §112, first paragraph and the objection to claim 48 for depending upon rejected claim 24.

Applicants have amended claims 1, and 20-23. Claim 1 is amended to correct a typographical error. Applicants submit that the claims as amended are supported throughout the specification, including at page 15, line 1 to page 16, line 23.

Applicants have added new claims 55-59. Applicants submit the newly presented claims are supported throughout the specification, including at pages 5-6, paragraphs 0013-0014.

Claims 2, 4, 27, and 30

Applicants have not cancelled claims 2, 4, 27, and 30. Further, Applicants acknowledge that claims 1, 3, 5-19, and 42-27 are currently allowed. Since generic claim 1 has been allowed, Applicants request that the Examiner search claims 2 and 4. Once generic claim 24 is found allowable, Applicants request that the Examiner search claims 27 and 30.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejects claims 20-26 and 28-29 under 35 U.S.C. §112, first paragraph, for allegedly not enabling an anti-IFN-α antibody light chain, an anti-IFN-α antibody heavy chain, and a fragment thereof. The Examiner objects to claim 48 as being dependent upon claim 24, which is rejected under 35 U.S.C. §112, first paragraph. Additionally, it is our understanding that the Examiner asserts that a complete heavy and a complete light chain variable region, each including 3 CDRs, are required for binding an antigen. Applicants respectfully traverse.

In establishing a *prima facie* case of nonenablement, the Examiner has the burden of setting forth a reasonable explanation of why the claimed scope is not enabled by the specification. *In re Wright*, 999 F.2d 1557, 1561-1562 (Fed. Cir. 1993). To meet the enablement requirement of 35 U.S.C. §112, first paragraph, a specification must contain a sufficient description to enable one skilled in the art to make and use the claimed invention (*See, e.g., Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); MPEP §2164.01).

A specification does not need to explicitly disclose every detail, and may omit what is well known in the art (*In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); MPEP 2164.01).

It is our understanding that the Examiner's rejection of the claims, including claim 24, for lack of enablement is based on the Examiner's contention that six CDRs are required for antigen binding. As a preliminary matter, Applicants note that claim 24 is directed to an anti-IFN-α antibody comprising at least one light chain or antigen binding fragment thereof comprising CDRs L1, L2, and L3, and at least one heavy chain or antigen binding fragment thereof comprising CDRs H1, H2, and H3. Indeed, claim 24 recites specific sequences associated with six CDRs. Applicants submit that claim 24 and dependent claims 25, 26, 28, 29 and 48 are enabled by the specification, and respectfully request withdrawal of the 112, first paragraph rejection.

Moreover, Applicants respectfully assert that the Examiner has not set forth a reasonable explanation of why the specification allegedly lacks an enabling disclosure. As we understand it, the Examiner contends that all six CDRs are required for antigen binding. In support of this position, the Examiner cites *Immunobiology* (6th edition, Janeway et al., *eds.*, p. 110-112). At page 111, the text recites the following:

> ***When*** the V_H and V_L domains are paired in the antibody molecule, the hypervariable loops from each domain are brought together, creating a single hypervariable site at the tip of each arm of the molecule. This is the binding site for antigen, the antigen-binding site or antibody combining site...Because CDRs from ***both V_H and V_L domains contribute to the antigen-binding site***, it is the combination of the heavy and light chain, and not either alone, that determines the final antigen specificity. [***emphasis added***]

Nowhere within the Examiner's citation does the reference state or support the Examiner's contention that all six CDRs are required for antigen binding. Therefore, the Examiner has not established that Applicants' specification is nonenabling.

In the previous response dated 1 April 2005, Applicants provided three representative articles that show that antigen binding fragments having only a single variable domain can bind antigen. One of the journal articles, Desmyter *et al.*, describes naturally occurring antibodies that only have a heavy chain variable domain and still bind to antigen. In the Cai *et al.* reference, the authors show that a variable heavy chain domain bound to a melanoma antigen with high affinity. These references show that at least a single variable domain can bind antigen.

Applicants submit that the Examiner has not set forth a reasonable explanation of why the specification allegedly lacks an enabling disclosure. Applicants submit that the specification as filed enables claims 20-26 and 28-29, and thereby claim 48. Applicants respectfully request withdrawal of the rejection and objection on this basis.

As discussed above, Applicants do not acquiesce to the rejection. However, in order to expedite prosecution, Applicants have amended claims 20-23. Applicants submit that claims as amended render the Examiner's rejection moot.

Based on the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph, rejection.

Interview

Applicants request an interview with the Examiner and his supervisor to resolve any outstanding issues remaining after submission of this Amendment.

SUMMARY

In view of the foregoing, Applicants believe that the claims are in condition for allowance and such action is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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